

REMARKS

Election/Restrictions

Claims 4, 32-34, 47-49, 51-56, 65, 66, 77, 78 and 89-103 have been withdrawn from consideration as being drawn to a non-elected invention and species of the invention. The Applicant has cancelled claims 89-103 without prejudice for submission and consideration in a continuing application. The Applicant has chosen to maintain the withdrawn claims 4, 32-34, 47-49, 51-56, 65, 66, 77 and 78 in the pending application for possible reinstatement upon the allowance of one or more generic base claims.

Specification

The Abstract of the disclosure has been objected to "because it contains implied language, i.e., 'This invention'". Appropriate correction has been made to the Abstract of the disclosure. Accordingly, withdrawal of the objection to the specification is respectfully requested.

Claims

Claims 28, 38, 43, 46, 62, 63, 74 and 81 have been amended to correct grammatical informalities as discovered by the Applicant, with none of the amendments having any limiting effect on the claims. Claims 42 and 45 have been rewritten in independent form and have been amended to more clearly define the present invention. Claim 59 has also been amended to more clearly define the present invention.

Claim Rejections – 35 USC §102 and §103

Claims 3, 15, 28-31, 35-46, 50, 59-64, 67, 70, 73-76 and 79-88 have been rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,491,724 to Ferree (hereafter "the Ferree reference"). Claims 2, 3, 28-31, 35-39, 42-46, 50, 59-60, 62-64, 67, 70, 73-76 and 79-88 have been rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,193,757 to Foley et al. (hereafter "the Foley reference"). Additionally, claims 57, 58, 68, 69, 71 and 72

have been rejected under 35 U.S.C. §103(a) as being unpatentable over the Ferree reference, and claims 57, 58, 68, 69, 71 and 72 have been rejected under 35 U.S.C. §103(a) as being unpatentable over the Foley reference.

Independent Claim 28 and Dependent Claims 2, 3, 15, 29-31, 35-41, 46, 50, 57 and 58

As indicated above, independent claim 28 has been rejected as being anticipated by the Ferree reference and the Foley reference. “[A]n invention is anticipated if the same device, including all the claim limitations, is shown in a single prior art reference. Every element of the claimed invention must be literally present, arranged as in the claim.” Richardson v. Suzuki Motor Co. Ltd., 868 F.2d 1226, 1236, 9 USPQ.2d 1913, 1920 (Fed. Cir. 1989). The claims must not be treated as “mere catalogs of separate parts, in disregard of the part-to-part relationships set forth in the claims and that give the claims their meaning.” Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Company et al., 730 F.2d 1452, 1459, 221 USPQ 481, 486 (Fed. Cir. 1984). As a result, a reference that coincidentally lists features of a claim without describing the claimed arrangement, relationship, and organization of such features cannot anticipate.

On pages 5 and 7 of the Office Action, it is stated that “[w]ith regard to the statement of intended use and other functional statements, they do not impose any structural limitations on the claims”. However, it is respectfully submitted that there is no prohibition to defining claimed structure in the terms of function. See, Manual of Patent Examining Procedure (MPEP) §2173.05(g) (citations including, Innova/Pure Water, Inc. v. Safari Water Filtration Sys. Inc., 381 F.3d 1111, 1117-20, 72 USPQ.2d 1001, 1006-08 (Fed. Cir. 2004) (interpreting functional language in apparatus claims and giving patentable weight thereto)). It is further noted that MPEP §2173.05(g) states “[a] functional limitation must be evaluated and considered, just like any other limitation in the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used.” In addition, the case of In re Mills, 16 USPQ.2d 1430 (Fed. Cir. 1990) involved functional limitations that were assigned patentable weight by the Federal Circuit. In this case, the claims were rejected as obvious because the difference between the claim and the cited references lay “solely” in the functional language of the claims. Id. at 1432. The Federal Circuit reversed on appeal, acknowledging that the difference between the

claim and the prior art lay specifically in the functional limitations. Nevertheless, the Federal Circuit held the claim nonobvious over the prior art based on the functional limitations. Id at 1433. Accordingly, functional language in a claim cannot be ignored for the purposes of patentability, and a prior art reference or combination of references must disclose or suggest the functional limitations of a claim, in addition to the structural limitations, to support a determination of unpatentability.

Independent claim 28 is directed to an expandable spacer for implantation between opposing endplates of adjacent vertebrae, with the spacer comprising a body composed of “a shape memory polymeric material” and comprising a peripheral sidewall, with “said body provided in a first configuration sized to overlay a first portion of a vertebral endplate wherein said body upon absorption of thermal energy expands to a second configuration sized to overlay a second portion of the vertebral endplate, said second portion having a greater area than the first portion”. As will be discussed in detail below, the language recited in independent claim 28 defines attributes of the spacer that are neither disclosed nor suggested by the Ferree reference of the Foley reference.

With regard to the Ferree reference, as an initial matter, although the implants 910 and 920 expand in height, the implants do not expand to overlay a greater area of the adjacent vertebral endplate, as recited in independent claim 28. Indeed, since the lateral or transverse dimensions of the vertebral bearing surfaces defined by the implants 910, 920 remain constant, the implants 910, 920 do not expand to overlay a greater area of the adjacent vertebral endplate. (See Figure 9B). Additionally, even assuming *arguendo* that the implants 910, 920 could be used in a manner wherein the lateral or transverse dimension is expanded (i.e., with the side surfaces of the implants 910, 920 abutting the vertebral endplates), the area of the vertebral endplate which the implant overlies would remain constant during such expansion. Indeed, although the relative position and orientation of the implant walls are varied, the walls overlie the same overall area of the vertebral endplates. This is most clearly illustrated in Figures 8B and 8C. Although the implant is transitioned to an expanded configuration, with the angular orientation of the upper wall changing relative to the lower wall, the walls still overlie the same overall area of the vertebral endplates. Indeed, since the cross-sectional area of each wall portion remains

constant, the walls can not overlie a greater area of the vertebral endplates. Although the outer dimension of the implant increases, the area of the implant overlying the vertebral endplate remains constant. Since the Ferree reference fails to disclose or suggest each of the elements and features recited in independent claim 28, the Applicant submits that independent claim 28 is patentable over the Ferree reference.

The Applicant further submits that the Ferree reference does not disclose that the implants are formed of “a shape memory polymer material”, as recited in independent claim 28. Instead, the Ferree reference discloses that that the implants may be formed of “shape memory alloys” (column 6, line 25), and that “[i]n terms of shape-memory alloys, . . . including, but not limited to alloys of copper and zinc, nickel titanium, silver and cadmium and other metals and materials, including Nitinol™” may be used to form the implants. (See column 6, lines 34-39). However, the Ferree reference does not disclose or suggest that the implants may be formed of a “shape memory polymer material”, as specifically recited in independent claim 28. The Applicant acknowledges that while the Ferree reference discloses that the implants may be formed of “carbon reinforced polymers . . . and nylon or other fiber or polymer materials used for radiolucent screen or mesh sleeve” (column 6, lines 24-27), there is no indication or suggestion of using shape memory polymer materials. Indeed, the patentee lists a litany of various polymer materials that may be used to form the implants, but does not indicate or suggest that shape memory polymer materials may be used. (See column 6, lines 27-34).

The Applicant further submits that the selection of a shape memory polymer material would not be a matter of mere design choice. Rather, as disclosed in the subject application, forming the spacer from a shape memory polymer (SMP) not only provides the spacer with the capability to laterally expand within the space between the adjacent vertebrae, but also provides the spacer with the ability to conform the vertebral bearing surfaces to the existing anatomical structure of the opposing vertebral endplates and/or to compress the spacer to a reduced height relative to the initial height. (See paragraph [0039]). Additionally, forming the spacer for a select SMP material allows the spacer to exhibit a compressive modulus similar to that of cancellous bone tissue. (See paragraph [0040]). These characteristics, as well as others, would not be provided via the use of a non-shape memory polymer material or a metallic shape memory

alloy material.

Additionally, albeit the Ferree reference discloses that the implants may be formed of a shape memory alloy, as clearly disclosed in the Ferree reference, the shape memory alloy (SMA) is utilized in a manner which takes advantage of the superelastic characteristic of the SMA material, as opposed to the shape-memory characteristic, which requires a corresponding change in temperature of the material to effect a change in shape. Specifically, the Ferree reference teaches that “the cage itself is preferably fashioned as a spring or constructed of a shape-memory material allowing the device to be compressed for implantation through a relatively small opening, but, once in place, the material naturally returns to its pre-implantation configuration”, (column 6, lines 6-11), and that the initial configuration of the implant “will be naturally resumed following a temporary compression”. (Column 6, lines 43-45; emphasis added). These passages are clearly directed to the superelastic characteristic of the SMA material wherein the implants are temporarily compressed to deform the implant for insertion into the disc space, followed by release of the compression force such that the implant will naturally expand to its initial configuration due to the superelastic nature of the SMA material. However, there is no mention whatsoever of providing thermal energy that is absorbed by the SMA material to correspondingly change the shape of the implant. As would be apparent to one of ordinary skill in the art, if the shape memory characteristic of a shape memory material were utilized (i.e., adding thermal energy to correspondingly change the shape of the implant), there would be no requirement to provide temporary compression of the implant to deform the implant and hold the implant in a compressed state prior to insertion into the disc space, followed by the subsequent release of the compression force to naturally and automatically expand the implant within the disc space via the superelastic characteristics of the SMA.

As indicated above, in order for an invention to be anticipated, each and every feature recited in the claim must be disclosed in a single prior art reference. Richardson v. Suzuki Motor Co. Ltd., 868 F.2d 1226, 1236, 9 USPQ.2d 1913, 1920 (Fed. Cir. 1989). Since the Ferree reference fails to disclose or even suggest that the implants are formed of a shape memory polymer material, as recited in independent claim 28, the Applicant submits that independent claim 28 is patentable over the Ferree reference. Additionally, since the Ferree reference fails to

disclose or even suggest that the implants are provided in a first configuration and wherein upon absorption of thermal energy the implant expands to a second configuration, as also recited in independent claim 28, the Applicant submits that independent claim 28 is patentable over the Ferree reference for this additional reason.

With regard to the Foley reference, the Applicant submits that, like the Ferree reference, the Foley reference likewise does not disclose the use of “a shape memory polymer material”, as recited in independent claim 28. Rather, the Foley reference specifically discloses that the spacers may be formed of “shape memory alloys” including nitinol. (See column 9, line 9 and column 10, lines 17-21). However, the Foley reference does not disclose or suggest that the spacers may be formed of a “shape memory polymer material”, as recited in independent claim 28. The Applicant acknowledges that while the Foley reference discloses that the spacers may also be formed of “composites and plastics” (column 9, lines 9-10), there is no indication or suggestion of using shape memory polymer materials. Additionally, as discussed above with regard to the Ferree reference, the Applicant further submits that the selection of a shape memory polymer material would not be a matter of mere design choice.

As indicated above, in order for an invention to be anticipated, each and every feature recited in the claim must be disclosed in a single prior art reference. Richardson v. Suzuki Motor Co. Ltd., 868 F.2d 1226, 1236, 9 USPQ.2d 1913, 1920 (Fed. Cir. 1989). Since the Foley reference fails to disclose or even suggest that the spacers may be formed of a shape memory polymer material, as recited in independent claim 28, the Applicant submits that independent claim 28 is patentable over the Foley reference.

For at least the foregoing reasons, the Applicant submits that independent claim 28 is patentable over both the Ferree and Foley references. Accordingly, withdrawal of the rejection of independent claim 28 and allowance of the same is respectfully requested. Claims 2, 3, 15, 29-31, 35-41, 46, 50, 57 and 58 depend either directly or indirectly from independent claim 28 and are submitted to be patentable for at least the reasons supporting the patentability of independent base claim 28.

Rewritten Independent Claim 42

Claim 42 has been rewritten in independent form and has been amended to more clearly recite the claimed invention. Rewritten independent claim 42 recites, among other elements and features, a body comprising a peripheral sidewall provided in a first configuration sized to overlay a first portion of a vertebral endplate and expands to a second configuration sized to overlay a second portion of the vertebral endplate, with “said second portion having a greater area than the first portion”, and “wherein the peripheral wall in the first configuration has a first cross-sectional area and the peripheral wall in the second configuration has a second cross-sectional area significantly greater than the first cross-sectional area”.

Neither the Ferree reference nor the Foley reference discloses the elements and features recited in independent claim 42. With regard to the Ferree reference, although the implants 910 and 920 expand in height, the implants do not expand to overlay a greater area of the adjacent vertebral endplate, as recited in independent claim 42. Indeed, since the lateral or transverse dimensions of the vertebral bearing surfaces defined by the implants 910, 920 remain constant, the implants 910, 920 do not expand to overlay a greater area of the adjacent vertebral endplate. (See Figure 9B). Additionally, even assuming arguendo that the implants 910, 920 could be used in a manner wherein the lateral or transverse dimension is expanded (i.e., with the side surfaces of the implants 910, 920 abutting the vertebral endplates), the cross-sectional area of the implant walls would remain constant during such expansion. Indeed, although the relative position and orientation of the implant walls are varied, the cross-sectional area of the walls remains unchanged. This is most clearly illustrated in Figures 8B and 8C. Although the implant is transitioned to an expanded configuration, with the angular orientation of the upper wall changing relative to the lower wall, there is no increase in the cross-sectional area of the walls. Indeed, since the cross-sectional area of each wall portion remains constant, the walls can not have a first configuration with a first cross-sectional area and an expanded second configuration having a second cross-sectional area significantly greater than the first cross-sectional area, as recited in independent claim 42.

With regard to the Foley reference, although the spacers 70, 80 and 100 expand from a first configuration to a second configuration, the cross-sectional area of the spacer walls remains

constant during such expansion. Although the relative position and orientation of the spacer walls varies, the cross-sectional area of the walls remains unchanged. This is most clearly illustrated in Figures 9B and 9C with regard to spacer 70, Figures 14 and 15 with regard to spacer 80, and Figures 18A and 18B with regard to spacer 100. In each of these spacer embodiments, as the spacer is transitioned to an expanded configuration, although the relative position and angular orientation of the wall portions are varied, there is no increase in the cross-sectional area of the walls. Since the cross-sectional area of each wall portion remains constant, the walls can not have a first configuration with a first cross-sectional area and an expanded second configuration having a second cross-sectional area significantly greater than the first cross-sectional area, as recited in independent claim 42.

For at least the foregoing reasons, the Applicant submits that rewritten independent claim 42 is patentable over both the Ferree and Foley references. Accordingly, withdrawal of the rejection of independent claim 42 and allowance of the same is respectfully requested. Claims 43 and 44 depend from rewritten independent claim 42 and are submitted to be patentable for at least the reasons supporting the patentability of independent base claim 42.

Rewritten Independent Claim 45

Claim 45 has been rewritten in independent form and has been amended to more clearly recite the claimed invention. Rewritten independent claim 45 now recites, among other elements and features, a body provided in a first configuration having a first width sized to overlay a first portion of a vertebral endplate and an expanded second configuration having a second width sized to overlay a second portion of the vertebral endplate, with “said second width being greater than the first width” and “wherein the body is provided in an original configuration having an original height and the body in the second configuration has a second height less than the original height”. Accordingly, the body of the spacer is expanded from a first width to a greater second width when transitioned to the second configuration and from an original height to a lesser second height when transitioned to the second configuration. Accordingly, the body of the spacer has a variable width dimension and a variable height dimension. Neither the Ferree reference nor the Foley reference discloses or suggests this combination of features. While the

implant disclosed in the Ferree reference arguably changes in height, the width dimension remains constant. Additionally, while the spacers disclosed in the Foley reference arguably changes in width, the height dimension remains constant. As a result, neither the Ferree reference nor the Foley reference discloses a spacer which changes in width and in height.

For at least the foregoing reasons, the Applicant submits that rewritten independent claim 45 is patentable over both the Ferree and Foley references. Accordingly, withdrawal of the rejection of independent claim 45 and allowance of the same is respectfully requested.

Independent Claim 59 and Dependent Claims 60-64, 67-76 and 79

Independent claim 59 has been amended to recite a deformable body comprising a first bearing surface, an opposite second bearing surface, and a peripheral sidewall positioned therebetween and defining an interior cavity, with “said first and second bearing surfaces each defining a first surface area when said body is in a first configuration”, and wherein said body expands to a second configuration upon absorption of thermal or radiation energy “with said first and second bearing surfaces each defining a second surface area in said second configuration significantly greater than said first surface area”.

Neither the Ferree reference nor the Foley reference disclose the elements and features recited in independent claim 59, as amended. With regard to the Ferree reference, although the implants 910 and 920 expand in height, the implants do not expand in such a manner wherein the vertebral bearing surfaces define a first surface area when in a first configuration and a second surface area in an expanded second configuration that is significantly greater than the first surface area, as recited in independent claim 49. Indeed, the vertebral bearing surfaces defined by the implants 910, 920 do not in any way change as the implants are expanded. (See Figure 9B). Additionally, even assuming arguendo that the implants 910, 920 could be used in a manner wherein the lateral or transverse dimension is expanded (i.e., with the side surfaces of the implants 910, 920 abutting the vertebral endplates), the surface area of the implant walls in contact with the vertebral endplates would remain constant during such expansion. Indeed, although the relative position and orientation of the implant walls are varied, the surface area of the walls in contact with the vertebral endplates remains unchanged. This is most clearly

illustrated in Figures 8B and 8C. Although the implant is transitioned to an expanded configuration, with the angular orientation of the upper wall changing relative to the lower wall, there is no increase in the surface area of the vertebral bearing surfaces. Accordingly, the walls can not have bearing surfaces defining a first surface area when the implant is in a first configuration and defining a second surface area in an expanded second configuration that is “significantly greater than said first surface area”, as recited in independent claim 59.

With regard to the Foley reference, although the spacers 70, 80 and 100 expand from a first configuration to a second configuration, the surface area of the vertebral bearing surfaces defined by the spacer walls remains constant during such expansion. Although the relative position and orientation of the spacer walls varies, the surface area of the vertebral bearing surfaces remains unchanged. This is most clearly illustrated in Figures 9B and 9C with regard to spacer 70, Figures 14 and 15 with regard to spacer 80, and Figures 18A and 18B with regard to spacer 100. In each of these spacer embodiments, as the spacer is transitioned to an expanded configuration, although the relative position and angular orientation of the wall portions are varied, there is no increase in the surface area of the vertebral bearing surfaces. Since the surface area of each wall portion remains constant, the walls can not have bearing surfaces defining a first surface area when the implant is in a first configuration and defining a second surface area in an expanded second configuration that is “significantly greater than said first surface area”, as recited in independent claim 59.

For at least the foregoing reasons, the Applicant submits that independent claim 59, as amended, is patentable over both the Ferree and Foley references. Accordingly, withdrawal of the rejection of independent claim 59 and allowance of the same is respectfully requested. Claims 60-64, 67-76 and 79 depend from independent claim 59 and are submitted to be patentable for at least the reasons supporting the patentability of independent base claim 59. Additionally, dependent claim 76 is patentable for reasons similar to those set forth above with regard to independent claim 45.

Independent Claim 80 and Dependent Claims 81-88

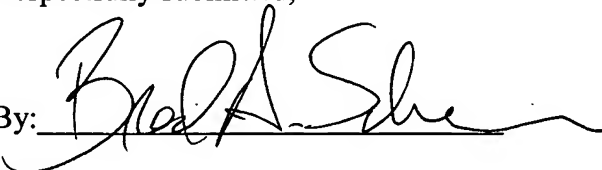
Independent claim 80 has been amended to depend from independent claim 28, and is submitted to be patentable for at least the reasons set forth above with regard to independent base claim 28. Additionally, claims 81-88 depend from claim 80, and are also submitted to be patentable for at least the reasons set forth above with regard to independent base claim 28. Accordingly, withdrawal of the rejection of claims 80-88 and allowance of the same is respectfully requested.

CONCLUSION

In view of the foregoing remarks and amendments, it is respectfully submitted that the Applicant's application is in condition for allowance with pending claims 2-4, 15 and 28-88.

Reconsideration of the subject application is respectfully requested. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

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